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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,376	10/19/2005	Ken Inose	TOYA114.011APC	6992
20995	7590	04/06/2007	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP			BERTAGNA, ANGELA MARIE	
2040 MAIN STREET			ART UNIT	PAPER NUMBER
FOURTEENTH FLOOR				
IRVINE, CA 92614			1637	
SHORTENED STATUTORY PERIOD OF RESPONSE		NOTIFICATION DATE	DELIVERY MODE	
3 MONTHS		04/06/2007	ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/06/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/553,376	INOSE ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Angela Bertagna	1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 07 February 2007.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-8 is/are pending in the application.
  - 4a) Of the above claim(s) 6-8 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-5 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 19 October 2005 is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 10/19/05; 8/18/06.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

*Election/Restrictions*

1. Applicant's election with traverse of Group I, claims 1-5, in the reply filed on February 2, 2007 is acknowledged. The traversal is on the ground(s) that the prior art of Gomez-Marquez does not teach all of the elements of claim 1 as amended, and therefore, the claims possess a special technical feature linking them over the prior art. This argument was not found persuasive, because as discussed in greater detail below, the prior art of Colpan et al. (US 6,383,393 B1) or Shigenaga et al. (Methods in Enzymology (1994) 234: 16-33) teaches all of the limitations of amended claim 1. Since the prior art of Colpan and Shigenaga anticipates the instant claim 1, the claims as amended lack a special technical feature linking them over the prior art, and therefore, a lack of unity requirement is proper.

The requirement is still deemed proper and is therefore made FINAL.

Claims 6-8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 2, 2007.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

*Priority*

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

*Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Colpan et al. (US 6,383,393 B1).

Regarding claim 1, Colpan teaches a method for isolating nucleic acids from a sample containing nucleic acids (see Example 7 at column 9, lines 10-52) comprising:

- (a) dissolving the sample in a buffer comprising at least one surfactant and at least one salt of a monovalent cation (column 9, lines 10-17, where Colpan teaches adding a solution containing Triton X-100 and potassium iodide to a blood sample)
- (b) heating the obtained solution (column 9, lines 17-20)
- (c) subjecting the heated solution to gel filtration (column 9, lines 30-39, where the gel matrix filters undesirable components from the solution; see also column 5, lines 34-58 for additional description of the filtration properties of the gel matrix filters used by Colpan)
- (d) collecting a fraction containing nucleic acids (column 9, lines 39-41).

Regarding claim 2, Colpan teaches that the surfactant is Triton X-100 (column 9, lines 16-17).

Regarding claim 3, Colpan teaches that the salt is NaCl (column 5, lines 20-25).

Regarding claims 4 and 5, Colpan teaches that the sample comprises eukaryotic cells, and more specifically, is a blood sample (column 9, lines 10-13).

5. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Shigenaga et al. (Methods in Enzymology (1994) 234: 16-33).

Regarding claims 1-3, Shigenaga teaches a method for isolating nucleic acids from a sample containing nucleic acids comprising:

(a) dissolving the sample in a buffer comprising at least one surfactant, specifically Triton X-100, and at least one salt of a monovalent cation, specifically NaCl (page 18, "Tissue Preparation" section, where Shigenaga teaches tissue homogenization in a buffer comprising 0.1 M NaCl and 0.5% (v/v) Triton X-100)

(b) heating the obtained solution (page 18, "Predigestion of Protein and RNA" section, where the digestion step is conducted at 50°C)

(c) subjecting the heated solution to gel filtration (pages 21-22, where Shigenaga teaches HPLC analysis of the DNA)

(d) collecting a fraction containing nucleic acids (pages 21-22).

Regarding claim 4, Shigenaga teaches that the sample comprises eukaryotic cells (see page 22, 2<sup>nd</sup> paragraph and Figure 1A, where Shigenaga teaches that the DNA is obtained from rat liver samples).

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***Conclusion***

No claims are currently allowable.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bille (US 2003/0215845 A1) teaches a method of nucleic acid purification from blood samples comprising the use of an extraction buffer containing NaCl and Triton X-100 and a gel filtration step (see abstract and paragraphs 116, 119, 125, and 131-134).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela Bertagna whose telephone number is 571-272-8291. The examiner can normally be reached on M-F, 7:30 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Angela Bertagna  
Examiner, Art Unit 1637  
March 16, 2007

amb

*[Signature]*  
**JEFFREY FREDMAN**  
**PRIMARY EXAMINER**

*31967*